

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE
 in its capacity as elected Office

Date of mailing (day/month/year) 08 March 2001 (08.03.01)	
International application No. PCT/US00/16433	Applicant's or agent's file reference -s063-0672WP
International filing date (day/month/year) 14 June 2000 (14.06.00)	Priority date (day/month/year) 14 June 1999 (14.06.99)
Applicant SWITZER, William, M. et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
 15 January 2001 (15.01.01)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer C. Cupello Telephone No.: (41-22) 338.83.38
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ENT COOPERATION TRE

RECEIVED
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FEB 06 2001

NOTIFICATION OF THE RECORDING OF A CHANGE NEEDLE & ROSENBERG

(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

MILLER, Mary
Needle & Rosenberg, P.C.
127 Peachtree Street, N.E.
Suite 1200
Atlanta, GE 30303-1811
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year)
24 January 2001 (24.01.01)

Applicant's or agent's file reference
-s063-0672WP 14114.0331P1

International application No.
PCT/US00/16433

IMPORTANT NOTIFICATION

International filing date (day/month/year)
14 June 2000 (14.06.00)

1. The following indications appeared on record concerning:

☐ the applicant ☐ the inventor ☒ the agent ☐ the common representative

Name and Address

MERCHANT, Mary, Anthony
Jones & Askew, LLP
2400 Monarch Tower
3424 Peachtree Road, N.E.
Atlanta, GA 30326
United States of America

State of Nationality

State of Residence

Telephone No.

(404) 949-2400

Facsimile No.

(404) 949-2499

Teleprinter No.

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☒ the person ☒ the name ☒ the address ☐ the nationality ☐ the residence

Name and Address

MILLER, Mary
Needle & Rosenberg, P.C.
127 Peachtree Street, N.E.
Suite 1200
Atlanta, GE 30303-1811
United States of America

State of Nationality

State of Residence

Telephone No.

(404) 688 0770

Facsimile No.

(404) 688 9880

Teleprinter No.

MLM/LSO/TMH
DOCKETED
By *DMW* Date *2/6/01*
Reviewed *tmh* *3/7/01*
Name / Date

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

☒ the receiving Office ☒ the designated Offices concerned
☐ the International Searching Authority ☐ the elected Offices concerned
☐ the International Preliminary Examining Authority ☐ other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Athina Nickitas-Etienne

Telephone No.: (41-22) 338.83.38

TENT COOPERATION TRE

PCT

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

MILLER, Mary
Needle & Rosenberg, P.C.
127 Peachtree Street, N.E.
Suite 1200
Atlanta, GE 30303-1811
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year) 24 January 2001 (24.01.01)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference -s063-0672WP	
International application No. PCT/US00/16433	International filing date (day/month/year) 14 June 2000 (14.06.00)

1. The following indications appeared on record concerning:		
<input checked="" type="checkbox"/> the applicant	<input checked="" type="checkbox"/> the inventor	<input type="checkbox"/> the agent <input type="checkbox"/> the common representative
Name and Address HENEINE, Walid 3815 Belle Glade Trail Lithonia, GA 30058 United States of America	State of Nationality LB	State of Residence US
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	
2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:		
<input type="checkbox"/> the person	<input type="checkbox"/> the name	<input checked="" type="checkbox"/> the address <input type="checkbox"/> the nationality <input type="checkbox"/> the residence
Name and Address HENEINE, Walid 2830 Woodland Park Drive Atlanta, GE 30345 United States of America	State of Nationality LB	State of Residence US
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	
3. Further observations, if necessary:		
4. A copy of this notification has been sent to:		
<input checked="" type="checkbox"/> the receiving Office	<input checked="" type="checkbox"/> the designated Offices concerned	
<input type="checkbox"/> the International Searching Authority	<input type="checkbox"/> the elected Offices concerned	
<input type="checkbox"/> the International Preliminary Examining Authority	<input type="checkbox"/> other:	

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Athina Nickitas-Etienne
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

MILLER, Mary
Needle & Rosenberg, P.C.
127 Peachtree Street, N.E.
Suite 1200
Atlanta, GE 30303-1811
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year) 24 January 2001 (24.01.01)	
Applicant's or agent's file reference -s063-0672WP	IMPORTANT NOTIFICATION
International application No. PCT/US00/16433	International filing date (day/month/year) 14 June 2000 (14.06.00)

1. The following indications appeared on record concerning:

☒ the applicant
 ☒ the inventor
 ☐ the agent
 ☐ the common representative

Name and Address SWITZER, William, M. 2001 Hollidon Road Decatur, GA 30033 United States of America	State of Nationality US	State of Residence US
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person
 ☐ the name
 ☒ the address
 ☐ the nationality
 ☐ the residence

Name and Address SWITZER, William, M. 5745 Redcoat Run Stone Mountain, GE 30087 United States of America	State of Nationality US	State of Residence US
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

☒ the receiving Office
 ☒ the designated Offices concerned
☐ the International Searching Authority
 ☐ the elected Offices concerned
☐ the International Preliminary Examining Authority
 ☐ other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer: Athina Nickitas-Etienne Telephone No.: (41-22) 338.83.38
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OUT-OF-FIRM PATENT COOPERATION TREATY

PCT

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

MERCHANT, Mary, Anthony
Jones & Askew, LLP
2400 Monarch Tower
3424 Peachtree Road, N.E.
Atlanta, GA 30326
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year) 10 October 2000 (10.10.00)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference -s063-0672WP	
International application No. PCT/US00/16433	International filing date (day/month/year) 14 June 2000 (14.06.00)

1. The following indications appeared on record concerning:

☒ the applicant ☒ the inventor ☐ the agent ☐ the common representative

Name and Address	State of Nationality	State of Residence
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☒ the person ☒ the name ☒ the address ☒ the nationality ☒ the residence

Name and Address FOLKS, Thomas, M. 3815 Belle Glade Trail Lithonia, GA 30058 United States of America RECEIVED OCT 23 2000 SCANNED	State of Nationality US	State of Residence US
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

3. Further observations, if necessary:

Additional applicant/inventor for the United States.

4. A copy of this notification has been sent to:

<input checked="" type="checkbox"/> the receiving Office	<input type="checkbox"/> the designated Offices concerned
<input checked="" type="checkbox"/> the International Searching Authority	<input type="checkbox"/> the elected Offices concerned
<input type="checkbox"/> the International Preliminary Examining Authority	<input type="checkbox"/> other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Athina Nickitas-Etienne Telephone No.: (41-22) 338.83.38
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REC'D 24 SEP 2001

WIPO

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

14

Applicant's or agent's file reference 14114.0331P1	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US00/16433	International filing date (day/month/year) 14/06/2000	Priority date (day/month/year) 14/06/1999
International Patent Classification (IPC) or national classification and IPC C12N7/02		
Applicant THE GOVERNMENT OF THE UNITED STATES OF AMERICA ...		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 9 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☒ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 15/01/2001	Date of completion of this report 20.09.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Julia, P Telephone No. +49 89 2399 8410 

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US00/16433

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-20 as originally filed

Claims, No.:

1-12 as originally filed

Drawings, sheets:

1/4-4/4 as originally filed

Sequence listing part of the description, pages:

1-3, filed with the letter of 27.02.01

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☒ furnished subsequently to this Authority in computer readable form.
- ☒ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US00/16433

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

II. Priority

1. ☐ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:

☐ copy of the earlier application whose priority has been claimed.

☐ translation of the earlier application whose priority has been claimed.

2. ☐ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid.

Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:
see separate sheet

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-11
	No:	Claims	12
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-12
Industrial applicability (IA)	Yes:	Claims	1-6, 8, 12
	No:	Claims	7, 9-11; see citations and explanations

2. Citations and explanations
see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US00/16433

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

1. Additional remarks to item I :

A "Sequence Listing" has been filed with the present application. This "Sequence Listing" comprises SEQ ID No.: 1 to SEQ ID No.: 7 (pages 1-3).

2. Additional remarks to item II :

The priority documents pertaining to the present application were not available at the time of establishing this international preliminary examination report (IPER). Hence, the current assessment is based on the assumption that all claims enjoy priority rights from the filing date of the priority document (14.06.99).

3. Additional remarks to item V :

The present application discloses a spumavirus or foamy virus (SFVHu-6) isolated from a human characterized by comprising one of SEQ ID No.: 1 (613 nucleotides, gag gene of SFVHu-6), 2 (616 nucleotides, gag gene virus isolate from chimpanzee B1), 3 (425 nucleotides, int gene of SFVHu-6), 4 (425 nucleotides, int gene virus isolate B1), 5 (240 nucleotides, ORF2 of SFVHu-6), 6 (240 nucleotides, ORF2 of virus isolate B1) or 7 (3576 nucleotides, 3' part of the env gene, complete ORF1 and ORF2 and the 5' end of the 3' LTR of SFVHu-6) or having ATCC Deposit No. VR-2635 (02.12.1998), the use of said virus as a vector for exogenous sequences / gene therapy (encoding a general antigen, antisense RNA, ribozyme RNA or decoy RNA), use for killing dividing (human and/or animal) cells (in vitro and/or in vivo, tumour formation or growth) and method detecting a spumavirus. The following documents have been cited in the International Search Report (ISR) :

i) US-5882912 (**D1**) a US-patent from the inventors of the present application and referred on pages 3 and 7 of the present application, discloses spumaviruses (SFVHu-1 and SFVHu-3) isolated from humans and which are characterized by being cross-reactive with SFV-3 antibodies. In particular, SFVHu-1 has structural and functional similarities to simian spumavirus of African green monkey origin, whereas SFV-Hu3 has similarities with a baboon-like simian spumavirus. The document refers to further embodiments which are in all identical to the ones of the present application.

ii) M. Schweizer et al., J. Virology 1997, Vol. 71(6), pages 4821-4824 (**D2**) and W. Heneine et al., Nature Medicine 1998, Vol. 4(4), pages 403-407 (**D3**) disclose simian foamy viruses isolated from infected human individuals.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US00/16433

According to the International Search Report, none of these documents disclose the specific sequences SEQ ID No.: 1-7 of the present application and thus, the subject matter of claims 1-11 fulfils the requirements of article 33 (2) PCT. However, the IPEA considers that the subject matter of claim 12 is not novel (article 33 (2) and (3) PCT) as far as the "antigens of the spumavirus of claim 1" are not clearly defined and thus, they embrace antigens shared by other known spumaviruses (see below under "Additional remarks to item VIII" too).

Moreover, in view of this prior art cited in the International Search Report and the general prior art concerning human and primate spumaviruses, the IPEA considers that the subject matter of claims 1-11 does not fulfil the requirements of article 33 (3) PCT. Primate and in particular human spumaviruses had already been isolated and fully characterized in the prior art (D1-D3). The technical problem underlying the application is considered to be the provision (characterization) of further human spumaviruses. The claimed subject matter solves said technical problem and it is considered to be novel (article 33 (2) PCT). However, this technical problem was already known in the prior art and specific nucleotide probes as well as specific antibodies for isolation of further human spumaviruses were generally available to the skilled person too. In the absence of any specific technical effect or advantageous feature of the disclosed SFVHu-6, said SFVHu-6 can only amount to an arbitrary selection amount all other possible human spumaviruses.

The attention of the Applicant is also drawn to the fact that the subject matter of claims 7 and 9-11 is directed to methods for treatment of the human or animal body (insofar the claimed subject matter comprises embraces a method in vivo too) and thus, it may be excluded from examination by Article 34(4)(a)(i) PCT in combination with Rule 67(iv) PCT too. Furthermore, for such a subject matter no unified criteria exist in PCT for the assessment whether it is industrially applicable or not. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject matter of claims to the use of a compound in medical treatment, but will allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

4. Additional remarks to item VII:

i) the attention of the Applicant is drawn to the fact that there is a serious inconsistency between the subject matter of the claims and the description. The description includes many embodiments which appear to fall outside the subject matter actually covered by the claims (see PCT Gazette-Section IV, Special Issue, PCT International Preliminary Examination Guidelines, 29.10.98, paragraph C-III, 4.3).

ii) the general wording "incorporated (by reference)" found in the description (page 7, etc...) for several documents cited in as relevant prior art or background art can arise problems clarity and interpretation and several Offices, such as the EPO, do not allow it (see PCT International Preliminary Examination Guidelines, C-II, 4.4 et seq.).

5. Additional remarks to item VIII :

The following objections are also raised under **Article 6 PCT** concerning the clarity of the claims :

i) a process feature in a product claim can only be relied on for establishing novelty over the prior art, where use of that process necessarily means that the product has a particular characteristic and the skilled person following the teaching of the application would inevitably achieve that characteristic, would be aware of that characteristic, and would discard any product not having it. The attention of the Applicant is also drawn to the fact that for a product by process claim no unified criteria exist in PCT. The EPO, for example, will allow these claims only if the product as such fulfils the requirements for patentability (inter alia that they are new and inventive) **and** there is no other information available in the application which could have enabled the Applicant to define the product satisfactorily by reference to its composition, structure or some other testable parameter. In particular, the feature "isolated from a human" in claim 1 is ambiguous (is a chimpanzee-derived virus isolated from an infected human a human or a chimpanzee virus ???) and it can lead to novelty problems.

The IPEA considers that the general definition of "spumavirus" characterizes a non-oncogenic and non-pathogenic retrovirus, establishing persistent infections, having a foamy or lace-like appearance and often accompanied by syncytium formation. Claim 1 requires as a further technical feature the presence of at least one of the sequences from

SEQ ID No.: 1-7. However, according to page 10 of the description SEQ ID No.: 2, 4 and 6 are from a SFV-infected source chimp and they have a 93-100% identity to the virus sequences determined from the "human case 6 SFCHu-6" SEQ ID No.: 1, 3 and 5. Thus, the IPEA considers that in the absence of any further (technical) requirement in claim 1 a (chimpanzee) SFV would fall under the scope of claim 1 as far as it can infect a human and therefore, in certain cases be isolated from a human (spumavirus, isolated from human and having at least SEQ ID No.: 2, 4 and 6) as also stated on pages 10-11 of the description ("...this near sequence identity confirms that the virus originated in chimpanzee B1 and was transmitted to Case 6 ...", "... Case 6 was severely bitten by chimpanzee B1 in 1977...", "... Sequences from Case 6 and chimpanzee B1 were indistinguishable (100%) identity) in both the integrase and gag regions ...").

ii) claim 7 is directed to a method of killing dividing cells, wherein these cells are not further characterized. Claim 10 being dependent on claim 7 is ambiguous as it further requires the infection to be capable of inhibiting tumour formation or growth (killing of tumour cells certainly inhibits tumour formation and/or growth).

iii) the subject matter of claim 12 is ambiguous as far as the "antigens of the spumavirus of claim 1" are not clearly characterized and/or defined. The spumavirus of claim 1 certainly comprises antigens which are not specific of the claimed spumavirus let alone of general spumaviruses or retroviruses. In particular, page 3 of the description of the present application refers to the presence of common antigens shared with the chimpanzee foamy virus SFV-6 (page 10 refers to 93-100% identity between SEQ ID No.: 2,4,6 from an SFV-infected source chimp to SEQ ID NO.: SEQ ID No.: 1, 3 , 5 from SFCHu-6) as well as with other human foamy or spumaviruses (SFVHu-1, SFVHu-3 page 7 of the present application) which have common antigens to the claimed spumavirus too (see figure 1 and paragraph (i) above). Thus, as far as these (specific) antigens of claim 12 (i.e. specific antigens of the claimed spumavirus) are the essential technical features of the claimed method and they are not clearly defined in the claim, this claimed method is not considered to fulfil the requirements of article 6 PCT.

iv) the applicant is reminded that on later stages of examination the corresponding certificate of the deposit ATCCC VR-2635 will be requested so as to examine whether said deposit has been performed under the conditions and/or requirements set out in Rule 13bis PCT.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US00/16433

v) the applicant is also reminded that according to article 6 PCT, the claimed subject matter has to be **fully** supported, i.e. not only formally (reference in the description) but also technically. In this respect, the present description does exemplified neither the use of the disclosed spumavirus as a vector (claims 3 to 6, disclosure of non-essential regions and/or regions suitable for introduction of exogenous sequences, efficient expression and/or production of encoded exogenous polypeptides, etc...) nor the killing of dividing cells (let alone tumour formation or growth).

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

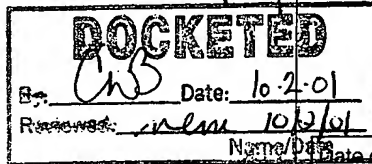
RECEIVED

OCT 01 2001

PCT
NEEDLE & ROSENBERG

To:

MILLER M.
NEEDLE & ROSENBERG P.C.
127 Peachtree Street
Suite 1200
Atlanta, GA 30303
ETATS-UNIS D'AMERIQUE



NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing
(day/month/year) 20.09.2001

Applicant's or agent's file reference
14114.0331P1

IMPORTANT NOTIFICATION

International application No.
PCT/US00/16433

International filing date (day/month/year)
14/06/2000

Priority date (day/month/year)
14/06/1999

Applicant
THE GOVERNMENT OF THE UNITED STATES OF AMERICA ...

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/

 European Patent Office
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Authorized officer

Hingel, W

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 14114.0331P1	<div style="display: flex; justify-content: space-between;"> <div> FOR FURTHER ACTION </div> <div> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) </div> </div>	
International application No. PCT/US00/16433	International filing date (day/month/year) 14/06/2000	Priority date (day/month/year) 14/06/1999
International Patent Classification (IPC) or national classification and IPC C12N7/02		
Applicant THE GOVERNMENT OF THE UNITED STATES OF AMERICA ...		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 9 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the report II <input checked="" type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input checked="" type="checkbox"/> Certain defects in the international application VIII <input checked="" type="checkbox"/> Certain observations on the international application 		
Date of submission of the demand 15/01/2001	Date of completion of this report 20.09.2001	
Name and mailing address of the international preliminary examining authority: <div style="display: flex; align-items: center;"> <div> European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 </div> </div>	Authorized officer Julia, P Telephone No. +49 89 2399 8410	



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US00/16433

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-20 as originally filed

Claims, No.:

1-12 as originally filed

Drawings, sheets:

1/4-4/4 as originally filed

Sequence listing part of the description, pages:

1-3, filed with the letter of 27.02.01

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☒ furnished subsequently to this Authority in computer readable form.
- ☒ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US00/16433

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

II. Priority

1. ☐ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:

- ☐ copy of the earlier application whose priority has been claimed.
- ☐ translation of the earlier application whose priority has been claimed.

2. ☐ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid.

Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:
see separate sheet

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-11
	No:	Claims	12
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-12
Industrial applicability (IA)	Yes:	Claims	1-6, 8, 12
	No:	Claims	7, 9-11; see citations and explanations

2. Citations and explanations
see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US00/16433

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US00/16433

1. Additional remarks to item I :

A "Sequence Listing" has been filed with the present application. This "Sequence Listing" comprises SEQ ID No.: 1 to SEQ ID No.: 7 (pages 1-3).

2. Additional remarks to item II :

The priority documents pertaining to the present application were not available at the time of establishing this international preliminary examination report (IPER). Hence, the current assessment is based on the assumption that all claims enjoy priority rights from the filing date of the priority document (14.06.99).

3. Additional remarks to item V :

The present application discloses a spumavirus or foamy virus (SFVHu-6) isolated from a human characterized by comprising one of SEQ ID No.: 1 (613 nucleotides, gag gene of SFVHu-6), 2 (616 nucleotides, gag gene virus isolate from chimpanzee B1), 3 (425 nucleotides, int gene of SFVHu-6), 4 (425 nucleotides, int gene virus isolate B1), 5 (240 nucleotides, ORF2 of SFVHu-6), 6 (240 nucleotides, ORF2 of virus isolate B1) or 7 (3576 nucleotides, 3' part of the env gene, complete ORF1 and ORF2 and the 5' end of the 3' LTR of SFVHu-6) or having ATCC Deposit No. VR-2635 (02.12.1998), the use of said virus as a vector for exogenous sequences / gene therapy (encoding a general antigen, antisense RNA, ribozyme RNA or decoy RNA), use for killing dividing (human and/or animal) cells (in vitro and/or in vivo, tumour formation or growth) and method detecting a spumavirus. The following documents have been cited in the International Search Report (ISR) :

i) US-5882912 (D1) a US-patent from the inventors of the present application and referred on pages 3 and 7 of the present application, discloses spumaviruses (SFVHu-1 and SFVHu-3) isolated from humans and which are characterized by being cross-reactive with SFV-3 antibodies. In particular, SFVHu-1 has structural and functional similarities to simian spumavirus of African green monkey origin, whereas SFV-Hu3 has similarities with a baboon-like simian spumavirus. The document refers to further embodiments which are in all identical to the ones of the present application.

ii) M. Schweizer et al., J. Virology 1997, Vol. 71(6), pages 4821-4824 (D2) and W. Heneine et al., Nature Medicine 1998, Vol. 4(4), pages 403-407 (D3) disclose simian foamy viruses isolated from infected human individuals.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US00/16433

According to the International Search Report, none of these documents disclose the specific sequences SEQ ID No.: 1-7 of the present application and thus, the subject matter of claims 1-11 fulfils the requirements of article 33 (2) PCT. However, the IPEA considers that the subject matter of claim 12 is not novel (article 33 (2) and (3) PCT) as far as the "antigens of the spumavirus of claim 1" are not clearly defined and thus, they embrace antigens shared by other known spumaviruses (see below under "Additional remarks to item VIII" too).

Moreover, in view of this prior art cited in the International Search Report and the general prior art concerning human and primate spumaviruses, the IPEA considers that the subject matter of claims 1-11 does not fulfil the requirements of article 33 (3) PCT. Primate and in particular human spumaviruses had already been isolated and fully characterized in the prior art (D1-D3). The technical problem underlying the application is considered to be the provision (characterization) of further human spumaviruses. The claimed subject matter solves said technical problem and it is considered to be novel (article 33 (2) PCT). However, this technical problem was already known in the prior art and specific nucleotide probes as well as specific antibodies for isolation of further human spumaviruses were generally available to the skilled person too. In the absence of any specific technical effect or advantageous feature of the disclosed SFVHu-6, said SFVHu-6 can only amount to an arbitrary selection amount all other possible human spumaviruses.

The attention of the Applicant is also drawn to the fact that the subject matter of claims 7 and 9-11 is directed to methods for treatment of the human or animal body (insofar the claimed subject matter comprises embraces a method in vivo too) and thus, it may be excluded from examination by Article 34(4)(a)(i) PCT in combination with Rule 67(iv) PCT too. Furthermore, for such a subject matter no unified criteria exist in PCT for the assessment whether it is industrially applicable or not. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject matter of claims to the use of a compound in medical treatment, but will allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US00/16433

4. Additional remarks to item VII:

i) the attention of the Applicant is drawn to the fact that there is a serious inconsistency between the subject matter of the claims and the description. The description includes many embodiments which appear to fall outside the subject matter actually covered by the claims (see PCT Gazette-Section IV, Special Issue, PCT International Preliminary Examination Guidelines, 29.10.98, paragraph C-III, 4.3).

ii) the general wording "incorporated (by reference)" found in the description (page 7, etc...) for several documents cited in as relevant prior art or background art can arise problems clarity and interpretation and several Offices, such as the EPO, do not allow it (see PCT International Preliminary Examination Guidelines, C-II, 4.4 et seq.).

5. Additional remarks to item VIII :

The following objections are also raised under **Article 6 PCT** concerning the clarity of the claims :

i) a process feature in a product claim can only be relied on for establishing novelty over the prior art, where use of that process necessarily means that the product has a particular characteristic and the skilled person following the teaching of the application would inevitably achieve that characteristic, would be aware of that characteristic, and would discard any product not having it. The attention of the Applicant is also drawn to the fact that for a product by process claim no unified criteria exist in PCT. The EPO, for example, will allow these claims only if the product as such fulfils the requirements for patentability (inter alia that they are new and inventive) **and** there is no other information available in the application which could have enabled the Applicant to define the product satisfactorily by reference to its composition, structure or some other testable parameter. In particular, the feature "isolated from a human" in claim 1 is ambiguous (is a chimpanzee-derived virus isolated from an infected human a human or a chimpanzee virus ???) and it can lead to novelty problems.

The IPEA considers that the general definition of "spumavirus" characterizes a non-oncogenic and non-pathogenic retrovirus, establishing persistent infections, having a foamy or lace-like appearance and often accompanied by syncytium formation. Claim 1 requires as a further technical feature the presence of at least one of the sequences from

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US00/16433

SEQ ID No.: 1-7. However, according to page 10 of the description SEQ ID No.: 2, 4 and 6 are from a SFV-infected source chimp and they have a 93-100% identity to the virus sequences determined from the "human case 6 SFCHu-6" SEQ ID No.: 1, 3 and 5. Thus, the IPEA considers that in the absence of any further (technical) requirement in claim 1 a (chimpanzee) SFV would fall under the scope of claim 1 as far as it can infect a human and therefore, in certain cases be isolated from a human (spumavirus, isolated from human and having at least SEQ ID No.: 2, 4 and 6) as also stated on pages 10-11 of the description ("...this near sequence identity confirms that the virus originated in chimpanzee B1 and was transmitted to Case 6 ...", "... Case 6 was severely bitten by chimpanzee B1 in 1977...", "... Sequences from Case 6 and chimpanzee B1 were indistinguishable (100%) identity) in both the integrase and gag regions ...").

ii) claim 7 is directed to a method of killing dividing cells, wherein these cells are not further characterized. Claim 10 being dependent on claim 7 is ambiguous as it further requires the infection to be capable of inhibiting tumour formation or growth (killing of tumour cells certainly inhibits tumour formation and/or growth).

iii) the subject matter of claim 12 is ambiguous as far as the "antigens of the spumavirus of claim 1" are not clearly characterized and/or defined. The spumavirus of claim 1 certainly comprises antigens which are not specific of the claimed spumavirus let alone of general spumaviruses or retroviruses. In particular, page 3 of the description of the present application refers to the presence of common antigens shared with the chimpanzee foamy virus SFV-6 (page 10 refers to 93-100% identity between SEQ ID No.: 2,4,6 from an SFV-infected source chimp to SEQ ID NO.: SEQ ID No.: 1, 3 ; 5 from SFCHu-6) as well as with other human foamy or spumaviruses (SFVHu-1, SFVHu-3 page 7 of the present application) which have common antigens to the claimed spumavirus too (see figure 1 and paragraph (i) above). Thus, as far as these (specific) antigens of claim 12 (i.e. specific antigens of the claimed spumavirus) are the essential technical features of the claimed method and they are not clearly defined in the claim, this claimed method is not considered to fulfil the requirements of article 6 PCT.

iv) the applicant is reminded that on later stages of examination the corresponding certificate of the deposit ATCCC VR-2635 will be requested so as to examine whether said deposit has been performed under the conditions and/or requirements set out in Rule 13bis PCT.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US00/16433

v) the applicant is also reminded that according to article 6 PCT, the claimed subject matter has to be **fully** supported, i.e. not only formally (reference in the description) but also technically. In this respect, the present description does exemplified neither the use of the disclosed spumavirus as a vector (claims 3 to 6, disclosure of non-essential regions and/or regions suitable for introduction of exogenous sequences, efficient expression and/or production of encoded exogenous polypeptides, etc...) nor the killing of dividing cells (let alone tumour formation or growth).

PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

MILLER M.
NEEDLE & ROSENBERG P.C.
127 Peachtree Street
Suite 1200
Atlanta, GA 30303
ETATS-UNIS D'AMERIQUE

RECEIVED

JUL 3 2001

PCT

NEEDLE & ROSENBERG

WRITTEN OPINION

(PCT Rule 66)

Date of mailing
(day/month/year) 24.07.2001

Applicant's or agent's file reference
14114.0331P1

REPLY DUE **within 1 month(s)**
from the above date of mailing

International application No.
PCT/US00/16433

International filing date (day/month/year)
14/06/2000

Priority date (day/month/year)
14/06/1999

International Patent Classification (IPC) or both national classification and IPC
C12N7/02

Applicant

THE GOVERNMENT OF THE UNITED STATES OF AMERICA ...

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☒ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain document cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

MLM / SSC / TMB

DOCKETED

By *[Signature]* Date *7/30/01*

Reviewed *[Signature]* Name/Date

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 14/10/2001.

Name and mailing address of the international preliminary examining authority:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized officer / Examiner

Julia, P

Formalities officer (incl. extension of time limits)
Zoglauer, H
Telephone No. +49 89 2399 8051



I. Basis of the opinion

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*):

Description, pages:

1-20 as originally filed

Claims, No.:

1-12 as originally filed

Drawings, sheets:

1/4-4/4 as originally filed

Sequence listing part of the description, pages:

1-3, filed with the letter of 27.02.01

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☒ furnished subsequently to this Authority in computer readable form.
- ☒ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

II. Priority

1. ☐ This opinion has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:

- ☐ copy of the earlier application whose priority has been claimed.
- ☐ translation of the earlier application whose priority has been claimed.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid.

Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:
see separate sheet

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- | | | | |
|-------------------------------|--------|---|--|
| 1. Statement | | | |
| Novelty (N) | Claims | 12; NO | |
| Inventive step (IS) | Claims | 1-12; NO | |
| Industrial applicability (IA) | Claims | 7, 9-11; see citations and explanations | |

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

1. Additional remarks to item I :

A "Sequence Listing" has been filed with the present application. This "Sequence Listing" comprises SEQ ID No.: 1 to SEQ ID No.: 7 (pages 1-3).

2. Additional remarks to item II :

The priority documents pertaining to the present application were not available at the time of establishing this preliminary opinion. Hence, the current assessment is based on the assumption that all claims enjoy priority rights from the filing date of the priority document (14.06.99).

3. Additional remarks to item V :

The present application discloses a spumavirus or foamy virus (SFVHu-6) isolated from a human characterized by comprising one of SEQ ID No.: 1 (613 nucleotides, gag gene of SFVHu-6), 2 (616 nucleotides, gag gene virus isolate from chimpanzee B1), 3 (425 nucleotides, int gene of SFVHu-6), 4 (425 nucleotides, int gene virus isolate B1), 5 (240 nucleotides, ORF2 of SFVHu-6), 6 (240 nucleotides, ORF2 of virus isolate B1) or 7 (3576 nucleotides, 3' part of the env gene, complete ORF1 and ORF2 and the 5' end of the 3' LTR of SFVHu-6) or having ATCC Deposit No. VR-2635 (02.12.1998), the use of said virus as a vector for exogenous sequences / gene therapy (encoding a general antigen, antisense RNA, ribozyme RNA or decoy RNA), use for killing dividing (human and/or animal) cells (in vitro and/or in vivo, tumour formation or growth) and method detecting a spumavirus. The following documents have been cited in the International Search Report (ISR) :

i) US-5882912 (**D1**) a US-patent from the inventors of the present application and referred on pages 3 and 7 of the present application, discloses spumaviruses (SFVHu-1 and SFVHu-3) isolated from humans and which are characterized by being cross-reactive with SFV-3 antibodies. In particular, SFVHu-1 has structural and functional similarities to simian spumavirus of African green monkey origin, whereas SFV-Hu3 has similarities with a baboon-like simian spumavirus. The document refers to further embodiments which are in all identical to the ones of the present application.

ii) M. Schweizer et al., J. Virology 1997, Vol. 71(6), pages 4821-4824 (**D2**) and W. Heneine et al., Nature Medicine 1998, Vol. 4(4), pages 403-407 (**D3**) disclose simian foamy viruses isolated from infected human individuals.

**WRITTEN OPINION
SEPARATE SHEET**

International application No. PCT/US00/16433

According to the International Search Report, none of these documents disclose the specific sequences SEQ ID No.: 1-7 of the present application and thus, the subject matter of claims 1-11 seems to fulfil the requirements of article 33 (2) PCT. However, the IPEA is of the opinion that the subject matter of claim 12 is not novel (article 33 (2) and (3) PCT) as far as the "antigens of the spumavirus of claim 1" are not clearly defined and thus, they embrace antigens shared by other known spumaviruses (see below under "Additional remarks to item VIII" too).

Moreover, in view of this prior art cited in the International Search Report and the general prior art concerning human and primate spumaviruses, the IPEA is of the opinion that the subject matter of claims 1-11 does not fulfil the requirements of article 33 (3) PCT. Primate and in particular human spumaviruses had already been isolated and fully characterized in the prior art (D1-D3). The technical problem underlying the application seems to be the provision (characterization) of further human spumaviruses. The claimed subject matter solves said technical problem and it is considered to be novel (article 33 (2) PCT). However, this technical problem was already known in the prior art and specific nucleotide probes as well as specific antibodies for isolation of further human spumaviruses were generally available to the skilled person too. In the absence of any specific technical effect or advantageous feature of the disclosed SFVHu-6, the IPEA is of the opinion that said SFVHu-6 only amounts to an arbitrary selection amount all other possible human spumaviruses.

The attention of the Applicant is also drawn to the fact that the subject matter of claims 7 and 9-11 is directed to methods for treatment of the human or animal body (insofar the claimed subject matter comprises embraces a method in vivo too) and thus, it may be excluded from examination by Article 34(4)(a)(i) PCT in combination with Rule 67(iv) PCT too. Furthermore, for such a subject matter no unified criteria exist in PCT for the assessment whether it is industrially applicable or not. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject matter of claims to the use of a compound in medical treatment, but will allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

4. Additional remarks to item VII:

i) the attention of the Applicant is drawn to the fact that there is a serious inconsistency between the subject matter of the claims and the description. The description seems to include many embodiments which appear to fall outside the subject matter actually covered by the claims (see PCT Gazette-Section IV, Special Issue, PCT International Preliminary Examination Guidelines, 29.10.98, paragraph C-III, 4.3).

ii) the general wording "incorporated (by reference)" found in the description (page 7, etc...) for several documents cited in as relevant prior art or background art can arise problems clarity and interpretation and several Offices, such as the EPO, do not allow it (see PCT International Preliminary Examination Guidelines, C-II, 4.4 et seq.).

5. Additional remarks to item VIII :

The following objections are also raised under **Article 6 PCT** concerning the clarity of the claims :

i) a process feature in a product claim can only be relied on for establishing novelty over the prior art, where use of that process necessarily means that the product has a particular characteristic and the skilled person following the teaching of the application would inevitably achieve that characteristic, would be aware of that characteristic, and would discard any product not having it. The attention of the Applicant is also drawn to the fact that for a product by process claim no unified criteria exist in PCT. The EPO, for example, will allow these claims only if the product as such fulfils the requirements for patentability (inter alia that they are new and inventive) **and** there is no other information available in the application which could have enabled the Applicant to define the product satisfactorily by reference to its composition, structure or some other testable parameter. In particular, the IPEA is of the opinion that the feature "isolated from a human" in claim 1 is actually ambiguous (is a chimpanzee-derived virus isolated from an infected human a human or a chimpanzee virus ???) and can lead to novelty problems.

The IPEA considers that the general definition of "spumavirus" characterizes a non-oncogenic and non-pathogenic retrovirus, establishing persistent infections, having a foamy or lace-like appearance and often accompanied by syncytium formation. Claim 1 requires as a further technical feature the presence of at least one of the sequences from

SEQ ID No.: 1-7. However, according to page 10 of the description SEQ ID No.: 2, 4 and 6 are from a SFV-infected source chimp and they have a 93-100% identity to the virus sequences determined from the "human case 6 SFCHu-6" SEQ ID No.: 1, 3 and 5. Thus, the IPEA considers that in the absence of any further (technical) requirement in claim 1 a (chimpanzee) SFV would fall under the scope of claim 1 as far as it can infect a human and therefore, in certain cases be isolated from a human (spumavirus, isolated from human and having at least SEQ ID No.: 2, 4 and 6) as also stated on pages 10-11 of the description ("...this near sequence identity confirms that the virus originated in chimpanzee B1 and was transmitted to Case 6 ...", "... Case 6 was severely bitten by chimpanzee B1 in 1977...", "... Sequences from Case 6 and chimpanzee B1 were indistinguishable (100%) identity) in both the integrase and gag regions ...").

ii) claim 7 is directed to a method of killing dividing cells, wherein these cells are not further characterized. Claim 10 being dependent on claim 7 seems to be ambiguous as it further requires the infection to be capable of inhibiting tumour formation or growth (killing of tumour cells certainly inhibits tumour formation and/or growth).

iii) the subject matter of claim 12 seems to be ambiguous as far as the "antigens of the spumavirus of claim 1" are not clearly characterized and/or defined. The spumavirus of claim 1 certainly comprises antigens which are not specific of the claimed spumavirus let alone of general spumaviruses or retroviruses. In particular, page 3 of the description of the present application refers to the presence of common antigens shared with the chimpanzee foamy virus SFV-6 (page 10 refers to 93-100% identity between SEQ ID No.: 2,4,6 from an SFV-infected source chimp to SEQ ID NO.: SEQ ID No.: 1, 3 , 5 from SFCHu-6) as well as with other human foamy or spumaviruses (SFVHu-1, SFVHu-3 page 7 of the present application) which have common antigens to the claimed spumavirus too (see figure 1 and paragraph (i) above). Thus, as far as these (specific) antigens of claim 12 (i.e. specific antigens of the claimed spumavirus) are the essential technical features of the claimed method and they are not clearly defined in the claim, this claimed method is not considered to fulfil the requirements of article 6 PCT.

iv) the applicant is reminded that on later stages of examination the corresponding certificate of the deposit ATCCC VR-2635 will be requested so as to examine whether said deposit has been performed under the conditions and/or requirements set out in Rule 13bis PCT.

**WRITTEN OPINION
SEPARATE SHEET**

International application No. PCT/US00/16433

v) the applicant is reminded that according to article 6 PCT, the claimed subject matter has to be **fully** supported, i.e. not only formally (reference in the description) but also technically. In this respect, the present description does exemplified neither the use of the disclosed spumavirus as a vector (claims 3 to 6, disclosure of non-essential regions and/or regions suitable for introduction of exogenous sequences, efficient expression and/or production of encoded exogenous polypeptides, etc...) nor the killing of dividing cells (let alone tumour formation or growth).

PATENT COOPERATION TREATY RECEIVED

(NR)

From the INTERNATIONAL SEARCHING AUTHORITY

APR 11 2001

PCT

To:
JONES & ASKEW, LLP
Attn. MERCHANT, Mary A.
2400 Monarch Tower
3424 Peachtree Road, N.E.
Atlanta, GA 30326
UNITED STATES OF AMERICA

NEEDLE & ROSENBERG

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT
OR THE DECLARATION

(PCT Rule 44.1)

RECEIVED

APR 03 2001

SCANNED

Applicant's or agent's file reference 03063-0672WP 14114.0331P1	Date of mailing (day/month/year) 30/03/2001
International application No. PCT/US 00/16433	International filing date (day/month/year) 14/06/2000
Applicant THE GOVERNMENT OF THE UNITED STATES OF AMERICA ...	

1. ☒ The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Fascimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

DOCKETED

By: CS Date: 4.11.01

Reviewed: MLM/SSC Name/Date

2. ☐ The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Geertruida Groeneveld-Van der Spek
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NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 03063-0672WP	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/US 00/16433	International filing date (day/month/year) 14/06/2000	(Earliest) Priority Date (day/month/year) 14/06/1999
Applicant THE GOVERNMENT OF THE UNITED STATES OF AMERICA ...		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☒ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☒ furnished subsequently to this Authority in computer readable form.

☒ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☒ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☒ None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 00/16433

A. CLASSIFICATION OF SUBJECT MATTER		
IPC 7	C12N7/02 A61P35/00 C12N15/48, A61K39/21	C12N7/01 C12N7/00 C12N15/867 A61K35/76 A61K48/00 C12Q1/70 //C07K14/15,
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) IPC 7 C12N		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) WPI Data, MEDLINE, BIOSIS, EPO-Internal, STRAND		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 882 912 A (SWITZER WILLIAM M ET AL) 16 March 1999 (1999-03-16) cited in the application the whole document	
A	SCHWEIZER M ET AL: "SIMIAN FOAMY VIRUS ISOLATED FROM AN ACCIDENTALLY INFECTED HUMAN INDIVIDUAL" JOURNAL OF VIROLOGY, THE AMERICAN SOCIETY FOR MICROBIOLOGY, US, vol. 71, no. 6, June 1997 (1997-06), pages 4821-4824, XP000917137 ISSN: 0022-538X the whole document --- -/--	
<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex.		
* Special categories of cited documents : *A* document defining the general state of the art which is not considered to be of particular relevance *E* earlier document but published on or after the international filing date *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) *O* document referring to an oral disclosure, use, exhibition or other means *P* document published prior to the international filing date but later than the priority date claimed *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. *Z* document member of the same patent family		
Date of the actual completion of the international search 20 March 2001		Date of mailing of the international search report 30/03/2001
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer Niemann, F

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 00/16433

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>HENBUBE W ET AL: "IDENTIFICATION OF A HUMAN POPULATION INFECTED WITH SIMIAN FOAMY VIRUSES" NATURE MEDICINE, NATURE PUBLISHING, CO, US, vol. 4, no. 4, April 1998 (1998-04), pages 403-407, XP000917012 ISSN: 1078-8956 the whole document -----</p>	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 00/16433

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claims 7,10,11, (in so far as it relates to in vivo methods), 9 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 00/16433

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5882912 A	16-03-1999	AU 6156298 A EP 1007640 A WO 9835024 A	26-08-1998 14-06-2000 13-08-1998